



## APPENDIX

### SECOND DECLARATION OF BIOMATERIALS ENGINEER AND CO-INVENTOR TIMOTHY A. RINGEISEN

I, Timothy A. Ringeisen, declare and say as follows:

That I am an inventor named on U.S. Patent Application Serial No. 10/729,146, entitled "Compressed High Density Fibrous Polymers Suitable for Implant";

That I am named as an inventor or co-inventor on 4 issued U.S. Patents and 13 pending U.S. patent applications;

That my formal education consists of a Bachelor of Science degree in Biology from Gustavus Adolphus College, and a Master of Industrial Hygiene from University of Minnesota;

That the above-identified patent application is subject to an obligation of assignment to Kensey Nash Corporation, a Delaware corporation with facilities in Exton, Pennsylvania;

That I am employed by Kensey Nash Corporation at its Exton facility as a Director of Biomaterials Research;

That I have 6 years experience with this company, and that I have 17 years experience overall as a Biomaterials Engineer;

That I am familiar with U.S. Patent No. 5,158,574 to Stone, and with U. S. Patent Application Publication No US2002/0127270 A1 to Li et al.;

That I am familiar with the invention claimed in the above-identified USSN 10/729,146 patent application;

That the claimed invention relates to a compressed polymeric fibrous implant where the fibers are at least partially aligned and arrange themselves in the form of plates or layers of aligned fibers;

That the partially aligned fibers of the instant invention may be prepared by charging a slurry featuring liquid, fibers and a lubricant into a mold, and compressing the slurry to remove fluid;

That I stated previously and I repeat my statement that the process of making the claimed articles never involves rotating a piston or a mold during compression;

That I stated previously and I repeat my statement that the articles of Stone and Li are fundamentally different from the claimed articles, and specifically, that the articles of Stone and Li do not include plates or layers of fibers;

That I now elaborate on why this is so, and why I stated previously that the rotations in Stone and Li would disrupt any plate or layer formation:

More specifically, that rotation of a solid within fibrous slurry creates flow within the slurry as a result of the viscous drag force acting on the slurry. This phenomenon is known as "Couette Flow" and is defined as the laminar flow of a viscous liquid in the space between two surfaces, one of which is moving relative to the other.

That as rotation continues, the movement of the slurry becomes "vortical" around the central axis. Streamlines, which can be thought of as rings, form as you move out from the center axis. As the streamlines form, fibers caught up in them align themselves in the direction of rotation and thus relatively parallel with adjacent fibers. The fibers associated with the inner streamlines have a shorter distance to travel than those forming the outer streamlines when making a circle around the rotating axis. More specifically stated, the circular streamlines toward the center can sweep out a given angle faster than those of outer streamlines, similar to how a runner on the inner lane of a circular track can make a complete loop faster than a runner on the outer lane when moving at the same speed. This well understood phenomenon is what causes any fiber oriented radial to the central axis to quickly turn until it is circumferential. The part of the fiber closest to the center is pulled along faster than every portion of the fiber extending outward, forcing the fiber to turn and become aligned with the direction of rotation (i.e., circumferential). The shear force caused by the rotation tears any grouping of fibers apart. Add to this that drag at the outer edge of the vessel slows the speed of rotation of the outer streamlines, creating even greater shear forces. Thus, in the case of Stone and Li, those fibers most closely associated with the rotating mandrel or piston would move faster than those closer to the non-moving surface, thereby tearing them apart.

That essentially every point within the volume of the slurry exposed to a rotating force is moving in a circular orbit about the common axis, but at a different rate, causing the fibers located at those points to align themselves with their nearest neighbors but preventing them from grouping together in the form of layers or plates.

That I understand that all statements made herein of my own knowledge are true and that statements made on information

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and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Further, declarant sayeth not.

Timothy A. Ringeisen  
Timothy A. Ringeisen

5-22-07  
Date